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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,614	08/11/2003	Katherine S. Tweden	7883.97-02	5399

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EXAMINER
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PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/639,614	Applicant(s) TWEDEN ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.  
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-37 and 41-68 is/are pending in the application.  
 4a) Of the above claim(s) 18-37 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 41-68 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/12/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group III and Species C in the reply filed on 1/28/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 18-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the written disclosure does not describe the obstruction as a "coronary blockage that is a partial blockage".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50,61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure (specification and drawings)

describes a blockage, but fail to explain to what degree or amount of blockage that is intended to be treated by the method.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 62-64,66,68 are rejected under 35 U.S.C. 102(a) as being anticipated by Sogard et al. (WO 98/12990). Fig. 3 shows a stent **10** having an outer surface with a covering **14** and Fig. 4 illustrates the inner surface can also have a covering **17**. In Fig. 6, Sogard shows both surfaces are covered. Sogard also discloses that an agent may be used with the stent, page 13, lines 9-13. Sogard additionally discloses the covering is ePTFE, page 12, lines 13-24. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the device is capable of providing blood flow from a heart chamber to a coronary vessel.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 65,67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sogard et al. (WO 98/12990) in view of Tartaglia et al. (5637113). Sogard is explained

supra. However, Sogard fails to disclose the agent is heparin. Tartaglia et al. teach the use of heparin with a covered stent, col. 6, lines 1-4. It would have been obvious to one of ordinary skill in the art to use heparin with the polymer as taught by Tartaglia in the stent of Sogard such that it prevents restenosis and thrombosis.

Claims 41,43,47-49,51-53,55,58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5429144) in view of Knudson et al. (5755682). Wilk discloses a stent placed in a myocardial site in the compressed state and then expanding the stent, col. 1, lines 54-63. Wilk also discloses (col. 8, lines 48-55) the stent has an inner and outer covering of natural tissue, Figs. 8A,8B,9. Wilk additionally discloses the method is used for passage of blood from the left ventricle to the coronary artery, col. 5, lines 46-48,53-56. Wilk also discloses deploying the stent by catheter, i.e. percutaneous, col. 6, lines 24-34. However, Wilk fails to disclose an agent is used with the stent to limit thrombus formation. Knudson et al. teach that agents that reduce restenosis, col. 10, lines 5-9. Since the agent is to prevent restenosis, it can be construed that the agent limits thrombus formation. Restenosis is a re-narrowing or blockage of an artery caused by a build-up of substances, i.e. blood clotting, platelets, that may eventually block the flow of blood. It would have been obvious to one of ordinary skill in the art to use an agent as taught by Knudson with the stent of Wilk such that it prevents restenosis and thrombus formation.

Claims 41-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5429144) in view of Lee (5123917). Wilk is explained supra. However, Wilk fails to disclose an agent, such as heparin to be used with the stent to limit thrombus

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formation. Lee teaches that agents such as heparin are used with a PTFE graft-stent to limit thrombus formation, col. 4, lines 51-61. It would have been obvious to one of ordinary skill in the art to use the heparin stent-graft of PTFE as taught by Lee in the method of Wilk such that it provides a graft that does not promote intimal tissue proliferation and limits thrombus formation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

